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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/407,806	09/28/1999	DENNIS MURPHY	DIVER1120-1	3254

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EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 05/20/2003

29

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application N .

09/407,806

Applicant(s)

MURPHY ET AL.

Examiner

David J. Steadman

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 April 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 17 January 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☒ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see attachment.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-9,13,14 and 17-45.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). 24.
10. ☐ Other: _____

ADVISORY ACTION

[1] Claims 1-9, 13, 14, and 17-45 are pending in the application.

[2] Claims 1-9, 13, 14, and 17-45 stand finally rejected.

[3] The request for reconsideration in the after final amendment of Paper No. 28, filed April 23, 2003, is acknowledged. The amendment would appear to overcome the objection and some of the rejections as set forth in Paper No. 23. However, the amendment does not place the claims in condition for allowance because the amendment would require further consideration of the claims as a new search would be required due to applicant's amendment to the sequence listing and further consideration of the claims would be required as a new rejection under 35 USC 112, second paragraph, would be required due the indefiniteness of the term "an alpha galactosidase activity" in the amended claims. The recitation of this term implies that the polypeptide encoded by the claimed polynucleotide can exhibit multiple activities and as such a skilled artisan would not recognize the scope of alpha galactosidase activity or activities to which applicant intends as being encompassed by the scope of the claim. See MPEP 714.13 regarding non-entry of after final amendments.

[4] The objection to claims 29-45 is maintained for the reasons of record and the reasons set forth below. The objection was fully explained in a previous Office action (see item 1 of Paper No. 23). Applicant argues (page 14 of Paper No. 28) the objections are overcome by amendment. However, in view of the non-entry of the amendment, the objection is maintained for the reasons of record. It is noted that the amendment would appear to overcome the objection.

[5] The rejection of claims 1-5, 6-9, 13, 14, 17-28, 32, 33, 40, 41, and 45 under 35 USC 112, second paragraph, as being indefinite in the recitation of "complementary" and "complement" is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a previous Office action (see item 3 of Paper No. 23). Applicant argues (pages 14-15 of Paper No. 28) the rejection is overcome by amendment. However, in view of the non-entry of the amendment, the rejection is maintained for the reasons of record. It is noted that the amendment would appear to overcome the rejection.

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[6] The rejection of claims 24, 32, 40, 41, and 45 under 35 USC 112, second paragraph, as being indefinite in the recitation of "hybridizes" is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a previous Office action (see item 4 of Paper No. 23). Applicant argues (page 15 of Paper No. 28) the rejection is overcome by amendment. However, in view of the non-entry of the amendment, the rejection is maintained for the reasons of record. It is noted that the amendment would not appear to overcome the rejection as amended claim 24 recites "hybridizing conditions *comprise*" (italics added for emphasis). The term "comprise" is open-ended claim language and a skilled artisan would therefore not recognize those hybridization conditions in addition to those recited in the claims that are encompassed by the scope of the claims.

[7] The rejection of claims 26, 32, 40, 41, and 45 under 35 USC 112, second paragraph, as being indefinite in the recitation of "stringent conditions" is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a previous Office action (see item 5 of Paper No. 23). Applicant argues (page 15 of Paper No. 28) the rejection is overcome by amendment. However, in view of the non-entry of the amendment, the rejection is maintained for the reasons of record. It is noted that the amendment would not appear to overcome the rejection as it is unclear from claim 26 as to those "stringent conditions" that can be used to identify those nucleic acids that are encompassed by the claims.

[8] The rejection of claims 29-31, 33-42, 44, and 45 under 35 USC 112, second paragraph, as being indefinite in the recitation of "portion of a polynucleotide" is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a previous Office action (see item 6 of Paper No. 23). Applicant argues (page 15 of Paper No. 28) the rejection is overcome by amendment. However, in view of the non-entry of the amendment, the rejection is maintained for the reasons of record. It is noted that the amendment would appear to overcome the rejection.

[9] The rejection of claims 29, 35-37, and 42 under 35 USC 112, second paragraph, as being indefinite in the recitation of "the fragment encodes a polynucleotide" is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a previous Office action (see

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item 7 of Paper No. 23). Applicant argues (page 15 of Paper No. 28) the rejection is overcome by amendment. However, in view of the non-entry of the amendment, the rejection is maintained for the reasons of record. It is noted that the amendment would appear to overcome the rejection.

[10] Claims 31-34, 38-41, 44, and 45 under 35 USC 112, second paragraph, as being indefinite in the recitation of "capable of identifying a polynucleotide encoding a polypeptide having alpha galactosidase activity" is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a previous Office action (see item 8 of Paper No. 23). Applicant argues (page 16 of Paper No. 28) the rejection is overcome by amendment. However, in view of the non-entry of the amendment, the rejection is maintained for the reasons of record. It is noted that the amendment would appear to overcome the rejection.

[11] The new matter rejection of claim 28 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a previous Office action (see item 9 of Paper No. 23). Applicant argues (page 16 of Paper No. 28) the rejection is overcome by amendment. However, in view of the non-entry of the amendment, the rejection is maintained for the reasons of record. It is noted that the amendment would appear to overcome the rejection.

[12] The rejection of claims 24, 25, and 27-45 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a previous Office action (see item 10 of Paper No. 23). Applicant argues (beginning at page 16 of Paper No. 28) the claimed genus of polynucleotides is described in the specification sufficient to show possession. Applicant argues that describing the genus in terms of its physico-chemical properties and function satisfies the written description requirement. Beginning at the second full paragraph at page 17, applicant argues that, based on example 14 of Revised Written Description Guidelines, the genus of claimed polynucleotides is described as procedures for making the species of polynucleotides encompassed by the claims are known in the art. Beginning at the third full paragraph at page 17, applicant argues the claimed nucleic acids are described by structure, a physico-chemical property, and function. Beginning at

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the third full paragraph at page 17, applicant cites case law allegedly supporting their arguments.

Beginning at the second full paragraph at page 18, applicant argues the claimed nucleic acids are defined via shared physical and structural properties sufficient to show possession. Beginning at the third full paragraph at page 18, applicant argues that claims drawn to a genus of polypeptides described by the physical characteristic of hybridization function have been issuing from the USPTO for many years and cite US Patent documents that allegedly support their argument. However, in view of the non-entry of the amendment, the rejection is maintained for the reasons of record. It is noted that the amendment would not appear to overcome the rejection. The claims as presented in the amendment of Paper No. 28 are unclear as to the particular function of the encoded polypeptide (see item 3 above) and are unclear as to the specific hybridization conditions used for hybridization (see item 6 above). It is further noted that example 14 of the Revised Written Description Guidelines is not directed to claims reciting hybridization conditions and is instead drawn to a claim reciting a *specific* percentage identity. Furthermore, the description of SEQ ID NO:3 would adequately describe the claimed variants of SEQ ID NO:3 (as recited in the sample claim) as the structure of SEQ ID NO:3 would constitute a substantial portion of each of the species within the claimed genus, i.e., at least 95% of SEQ ID NO:3 must be present in each of the species of the claimed genus. Regarding those claims drawn to a genus of nucleic acids encompassing nucleic acid fragments (e.g., claim 29), it is noted that such fragments do *not* constitute a substantial portion of the genus and the disclosed species fail to be representative of the entire genus of claimed nucleic acids. Presently, hybridization language does not preclude a claim from satisfying the written description requirement. In this case the recited structural characteristic and function shared by all members of the species is insufficient to adequately describe the entire genus of claimed polynucleotides.

[13] The rejection of claims 24, 25, and 27-45 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a previous Office action (see item 11 of Paper No. 23). Applicant argues (beginning at page 19 of Paper No. 28) the specification enables the entire scope of polynucleotides in view of the alleged high level of skill in the art. Applicant argues (beginning at the bottom of page 19 of Paper No. 28) undue experimentation would

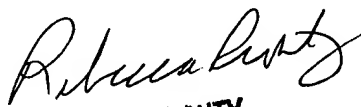
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not be required to make and use the entire scope of claimed polynucleotides. Applicant argues (beginning at the first full paragraph of page 20 of Paper No. 28) screening a large number of negatives does not constitute undue experimentation. Applicant argues (beginning at the second full paragraph at page 20 of Paper No. 28) the specification provides hybridization conditions and alpha galactosidase assay that enable a skilled artisan to make and use the entire scope of claimed polynucleotides and provided with the disclosed polynucleotide structure, such experimentation would not be undue. Applicant argues (beginning at the bottom of page 20 of Paper No. 28) that claims drawn to a genus of polypeptides described by the physical characteristic of hybridization function have been issuing from the USPTO for many years and cite US Patent documents that allegedly support their argument. However, in view of the non-entry of the amendment, the rejection is maintained for the reasons of record. It is noted that the amendment would not appear to overcome the rejection. It is noted that, as the claims are presented in the amendment of Paper No. 28, it is unclear as to the particular function of the encoded polypeptide (see item 3 above) and it is unclear as to specific hybridization conditions used in the hybridization (see item 6 above). Regarding those claims broadly encompassing nucleic acid fragments (e.g., claim 29), one of skill in the art would recognize that such fragments are highly unlikely to encode polypeptides with alpha galactosidase activity and the specification fails to disclose those amino acids of SEQ ID NO:4 that are necessary for catalytic activity. There is no guidance in the specification that the polynucleotide fragments encompassed by the amended claims would encode polypeptides having alpha galactosidase activity if such fragments were found within a larger encoding polynucleotide. Furthermore, the specification provides no guidance or working examples to demonstrate that such fragments found within a larger polynucleotide would encode polypeptides with alpha galactosidase activity. Thus, even if a skilled artisan were to use screening techniques to isolate other polynucleotides comprising such fragments, a high degree of unpredictability remains as to whether such polynucleotides would encode polypeptides having alpha galactosidase activity. In view of the broad scope of the claims, the lack of guidance and working examples, and the high degree of unpredictability, an undue amount of experimentation would be required to make and use the claimed polynucleotides.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652


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PRIMARY EXAMINER
~~GROUP 1000~~
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